

REMARKS

Claims 1-9 and 11 are currently pending. Claims 10 and 13-36 have been previously cancelled without prejudice. Claim 12 has been previously withdrawn without prejudice. Claims 1-3 have been amended. No new matter is introduced.

Rejection under 35 USC § 112, Second Paragraph

Claims 2-3 are rejected under 35 USC § 112, second paragraph, for the reasons noted at page 3 of the Office Action. To expedite prosecution, the term "said upper cover" has been amended to now recite "said cover" as noted in the Listing of the Claims section of this paper.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 2-3 under 35 USC § 112, second paragraph.

First Rejection Under 35 USC § 103(a)

Claims 1, 3-6 and 9 are rejected under 35 USC § 103(a) as being rendered obvious by European Patent No. 0 882 981 A1 to Caillat et al. (hereinafter "Caillat EP") or by U.S. Patent 3,126,800 to Caillat et al. (hereinafter "Caillat US"), each in view of U.S. Patent 4,988,617 to Landegren et al. (hereinafter "Landegren") for the reasons noted at pages 4-7 of the Office Action. Applicants respectfully traverse this rejection for the reasons noted below.

In particular, the Office Action states at page 5, second paragraph, in relevant part that (apparently in the context of the foregoing asserted obviousness rejection) that:

It is noted that the courts have held that 'while features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function' [and citing] *In re Schreiber*, 128 F.3d 1473, 1477-78, [parallel cite omitted] (Fed. Cir. 1997). In addition, 'Apparatus claims cover what a device is, not what a device does' [and citing] *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, [parallel cite omitted] (Fed. Cir. 1990). . . . Therefore, the various uses recited in claim 1 . . . fail to define . . . structural elements . . . [such that] the claim is obvious over the prior art. [(Office Action at page 5, second full paragraph; bold with underlining emphasis added.)]

However, the *In re Schreiber* decision cited at 128 F.3d, 1473, 1477-78 (Fed. Cir. 1977) nowhere states or asserts the quotation relied on in the Office Action that "while features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than

function". Such attributed quotation is nowhere to be found in *In re Schreiber*. For the Examiner's convenience, a copy of *In re Schreiber* is enclosed.

Furthermore, the decision in *In re Schreiber* relates to the issue of inherent anticipation in that a reference that contains all the same elements of a claimed invention – regardless of recognized use of all the same elements - inherently anticipates the claimed invention. So, *In re Schreiber* is limited to an anticipation rejection – and – does not apply as here to the asserted obviousness rejection.

Moreover, the claimed invention properly utilizes functional language in conjunction with an element of Applicants' rejected claims. Namely, Applicants' rejected claim 1 specifies that the measuring electrodes "measure an electric current variation between the measuring electrodes and a common electrode corresponding to hybridization with PCR products or oligonucleotides and sufficient to detect point mutations" as noted in the **Listing of the Claims** section of this paper. Such recitation is consistent with that permitted under MPEP § 2173.05(g) which states in relevant part:

A functional limitation is an attempt to define something by what it does, rather than by what it is (e.g., as evidenced by its specific structure or specific ingredients). There is nothing inherently wrong with defining some part of an invention in functional terms. Functional language does not, in and of itself, render a claim improper. *In re Swinehart*, 439 F.2d 210, 169 USPQ 226 (CCPA 1971). [(Underlining emphasis added.)]

A functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used. A functional limitation is often used in association with an element, ingredient, or step of a process to define a particular capability or purpose that is served by the recited element, ingredient or step. >In *Innova/Pure Water Inc. v. Safari Water Filtration Sys. Inc.*, 381 F.3d 1111, 1117-20, 72 USPQ2d 1001, 1006-08 (Fed. Cir. 2004), the court noted that the claim term "operatively connected" is "a general descriptive claim term frequently used in patent drafting to reflect a functional relationship between claimed components," that is, the term "means the claimed components must be connected in a way to perform a designated function." "In the absence of modifiers, general descriptive terms are typically construed as having their full meaning." *Id.* at 1118, 72 USPQ2d at 1006. In the patent claim at issue, "subject to any clear and unmistakable disavowal of claim scope, the term 'operatively connected' takes the full breath of its ordinary meaning, i.e., 'said tube [is] operatively connected to said cap' when the tube and cap are arranged in a manner capable of performing the function of filtering." *Id.* at 1120, 72 USPQ2d at 1008.< [(Underlining emphasis added.)]

Consistent with the functional scope of claim 1 previously presented (so as not to introduce new matter), Applicants have now amended claim 1 to recite the "operatively connected" language approved in *Innova/Pure Water Inc. v. Safari Water Filtration Sys. Inc.*, 381 F.3d 1111, 1117-20 (Fed. Cir. 2004). Thus, claim 1 now recites the language "said plurality of measuring electrodes operatively connected at a bottom of said space sufficient to measure an electric current variation between the measuring electrodes and a common electrode corresponding to hybridization with PCR products or oligonucleotides and sufficient to detect point mutations" as noted in the Listing of the Claims section of this paper.

In view of the foregoing deficiencies in the Office Action inaccurately citing in *In re Schreiber* for a proposition/assertion not supported by that case and contrary to MPEP § 2173.05(g) (noted above) – Applicants respectfully submit that the functional language of Applicants' rejected claims cannot be ignored. The functional language of Applicants' rejected claims defines the structure of the measuring electrodes recited in the rejected claims.

Additionally, rejected claim 5 recites the language "The gene detecting chip according to claim 1, wherein said common electrode is arranged so as not to contact the measuring electrodes" as noted in the Listing of the Claims section of this paper. In contrast, Fig. 2 of Caillat US clearly illustrates and describes that the "analysis electrodes" 12a and 12b are connected to the "addressing electrode" 14 via electrical interconnections between them, respectively, as noted in relevant part (reproduced from Caillat US) below:

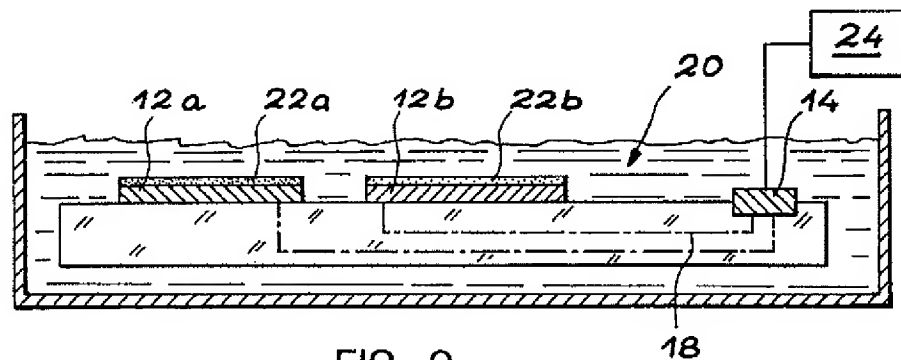


FIG. 2

The chip 10 includes two electrodes called analysis electrodes 12a and 12b and addressing electrodes 14 only one of which is visible. [(Caillat US at col. 1, lines 26-28; underlining emphasis added.)]

* * *

The analysis electrodes 12a and 12b are made of a metal such as, for example gold or platinum. They are insulated from one another on a substrate wafer 16. The electrical links between the analysis

electrodes 12a, 12b and the addressing electrodes are arranged in the substrate 16 and are indicated very schematically by reference number 18. [(Caillat US at col. 1, lines 45-50; underlining emphasis added.)]

Thus, with respect to rejected claim 5, Caillat US describes electrical connection as noted above – whereas rejected claim 5 specifies that the “common electrode is arranged so as not to contact the measuring electrodes” as noted in the Listing of the Claims section of this paper.

Furthermore, Caillat US does not rely upon electrodes that measure the current variation to detect point mutations as recited in Applicants’ rejected claims, but instead relies on an entirely different light detection method as noted in Caillat US with reference to Fig. 4 thereof (as reproduced below) in relevant part:

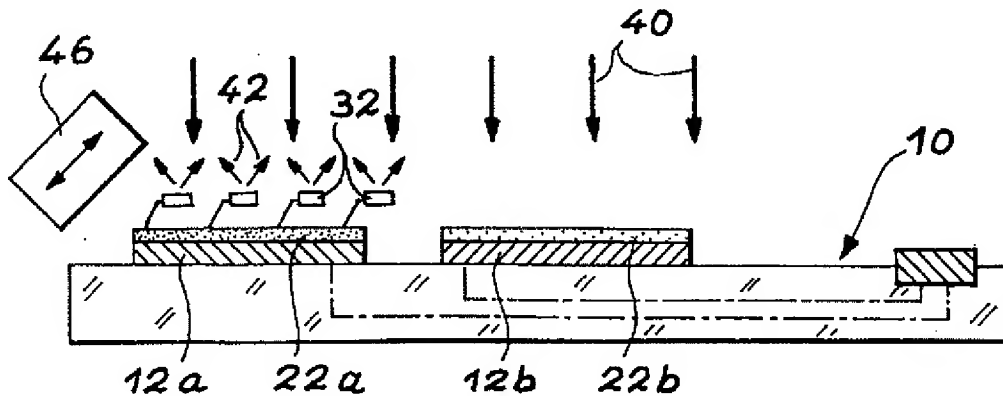


FIG. 4

In the example described in FIG. 4, the chip 10 is analysed by a fluorescence detection method. Such a method is particularly suitable when the target molecules are labelled with a fluorescent labelling product called a fluophor.

However, it is also possible to envisage other methods of analysis such as electrical measurement methods using impedance measurements, measurement by microbalance, optical measurement using a change in refractive index and analytical methods using radioactive labelling.

As shown in FIG. 4, the chip assembly 10 is subjected to light radiation 40 of a first wavelength coming from a light source which has not been represented.

The labelled target molecules absorb the light radiation 40 and emit a light radiation 42 with a second characteristic wavelength which is different to the first wavelength.

A detection system 46, sensitive to the second wavelength permits the detection of the light re-emitted from the electrodes carrying the target molecules labelled by the fluorescent product. It is therefore possible, by knowing the nature of the reactants or the probe molecules previously deposited on each electrode to determine the

components of the analyte which are fixed there. [(Caillat US at col. 2, lines 40-55; underlining emphasis added.)]

In similar fashion, the apparatus of Caillat US likewise relies on the use of a fluorescent detection method as noted therein (and reproduced below) in relevant part:

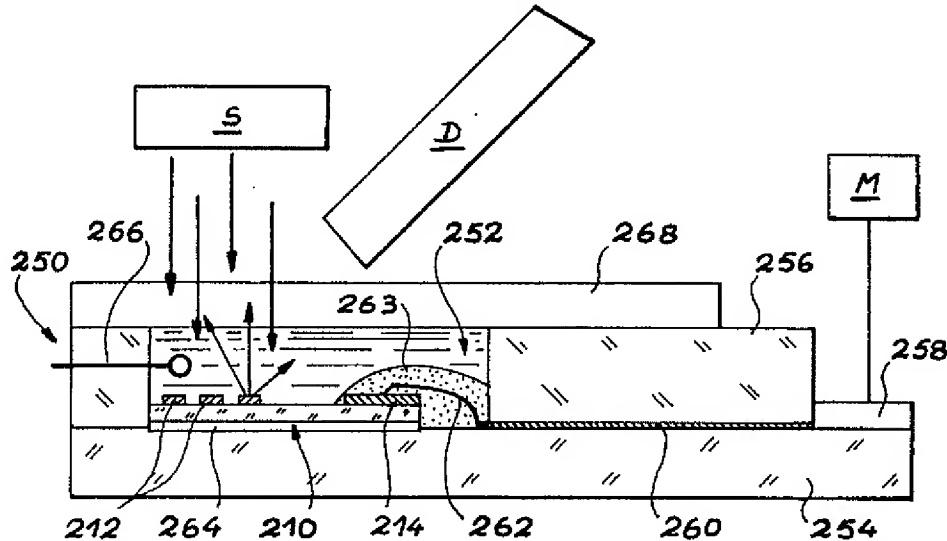


FIG. 5

[With respect to Fig. 5,] [w]hen the analysis method is a method of fluorescence measurement such as the one previously described, the cover 268 can advantageously be constituted by a sheet of glass which allows incident radiation coming from a light source S to pass through it and allows the fluorescence radiation to pass to a detector D. [(Caillat US at col. 5, lines 53-58; underlining emphasis added.)]

Of course, Caillat US does not disclose, teach or suggest the ability to detect point mutations as noted in Applicants' specification and as described by Applicants in their Amendment filed on May 21, 2007. To that end, the relevant remarks of Applicants' May 21, 2007 remarks are incorporated herein by reference without having to repeat the same. See Applicants' May 21, 2007 Amendment Remarks at pages 11 and 12, and the relevant Applicants' specification pages corresponding thereto, for example.

So, while Applicants' clearly demonstrate how with improved throughput they can detect point mutations without having to sequence the entire gene segment, Caillat US does not do so. Simply because Caillat US describes the use of electrodes, Caillat US does not describe, teach or suggest how its electrodes are "configured" or "operationally connected" to "to measure an electric current variation between the measuring electrodes and a common electrode corresponding to hybridization with PCR products or oligonucleotides and sufficient to detect point mutations" as noted in the Listing of the Claims section of this paper.

The foregoing remarks illustrate the enormous deficiencies of the Caillat US cited reference and also those of the corresponding Caillat EP reference. None of the foregoing

deficiencies of Caillat US (and/or Caillat EP) are rectified by combining Caillat US (and/or Caillat EP) with the cited secondary reference (Landegren) because (for example) Landegren is relied to assertedly disclose immobilized oligonucleotides.

The further point that "85% of mutations in the human genome are point mutations" as recited in the last sentence appearing at page 5 of the Office Action – does not by itself or in combination with Caillat US (and/or Caillat EP) convert the observation of 85% occurrence to a disclosure, teaching or suggestion of Applicants' claimed invention with the improved throughput Applicants are able to surprisingly and unexpectedly achieve – without having to sequence the entire gene segment to detect point mutations.

Moreover, Landegren Example 5 states that the "assay was performed essentially as in example 1 except that the final concentration of NaCl and T4 DNA ligase in the assay [were] varied." See Landegren at col. 18, lines 19-22. Furthermore, reviewing Example 1 thereof, Landegren describes the use of biotinylated oligonucleotides using beads and autoradiography having nothing whatsoever to do with Applicants' recited electrodes "to measure an electric current variation between the measuring electrodes and a common electrode corresponding to hybridization with PCR products or oligonucleotides and sufficient to detect point mutations" as noted in the Listing of the Claims section of this paper.

Thus, reliance on Landegren does not rectify the deficiencies of Caillat US (and/or Caillat EP corresponding to Caillat US). For at least these reasons, Applicants respectfully submit that claims 1, 3-6 and 9 are non-obvious and patentable over Caillat US (and/or Caillat EP) in view of Landegren. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1, 3-6 and 9 under 35 USC § 103(a) over Caillat US (and/or Caillat EP) in view of Landegren.

Second Rejection Under 35 USC § 103(a)

Claims 2 and 11 are rejected under 35 USC § 103(a) as being anticipated by Caillat EP or by Caillat US, each in view of Landegren as applied to claim 1, and further in view of U.S. Patent No. 5,587,128 to Wilding et al. (hereinafter "Wilding") for the reasons noted at pages 7-9 of the Office Action. Applicants respectfully traverse this rejection for the reasons noted below.

In particular, Applicants reiterate their above-noted remarks relating to the rejection of claims 1, 3-6 and 9 and the above-noted deficiencies of Caillat US (and/or Caillat EP) in view of Landegren – by incorporating those remarks herein without having to repeat the same and applying the same to the instant rejection of dependent claims 2 and 11 – noting that claims 2 and 11 (like claims 3-6 and 9) all depend ultimately from claim 1. Applicants further note that Wilding is relied upon in the Office Action to assertedly teach "holes."

However, in view of the foregoing, Applicants note that such (or other) asserted reliance on Wilding does not rectify the above-noted deficiencies of Caillat US (and/or Caillat EP) in view of Landegren. For at least these reasons, Applicants respectfully submit that claims 2 and 11 are non-obvious and patentable over Caillat US (and/or Caillat EP) in view of Landegren and/or Wilding. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 2 and 11 under 35 USC § 103(a) over Caillat US (and/or Caillat EP) in view of Landegren and/or Wilding.

Third Rejection Under 35 USC § 103(a)

Claims 7 is rejected under 35 USC § 103(a) as being anticipated by Caillat EP or by Caillat US, each in view of Landegren as applied to claim 1, and further in view of U.S. Patent No. 5,632,957 to Heller et al. (hereinafter "Heller") for the reasons noted at pages 9-10 of the Office Action. Applicants respectfully traverse this rejection for the reasons noted below.

In particular, Applicants reiterate their above-noted remarks relating to the rejection of claims 1, 3-6 and 9 and the above-noted deficiencies of Caillat US (and/or Caillat EP) in view of Landegren – by incorporating those remarks herein without having to repeat the same and applying the same to the instant rejection of dependent claim 7 – noting that claim 7 (like claims 3-6 and 9) depends ultimately from claim 1. Applicants further note that Heller is relied upon in the Office Action to assertedly teach "wiring."

However, in view of the foregoing, Applicants note that such (or other) asserted reliance on Heller does not rectify the above-noted deficiencies of Caillat US (and/or Caillat EP) in view of Landegren. For at least these reasons, Applicants respectfully submit that claim 7 is non-obvious and patentable over Caillat US (and/or Caillat EP) in view of Landegren and/or Heller. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 7 under 35 USC § 103(a) over Caillat US (and/or Caillat EP) in view of Landegren and/or Heller.

Fourth Rejection Under 35 USC § 103(a)

Claims 8-9 are rejected under 35 USC § 103(a) as being anticipated by Caillat EP or by Caillat US, each in view of Landegren as applied to claim 1, and further in view of PCT International Application No. WO 98/12539 to Wohlstadter et al. (hereinafter "Wohlstadter") for the reasons noted at pages 10-11 of the Office Action. Applicants respectfully traverse this rejection for the reasons noted below.

In particular, Applicants reiterate their above-noted remarks relating to the rejection of claims 1, 3-6 and 9 and the above-noted deficiencies of Caillat US (and/or Caillat EP) in view of Landegren – by incorporating those remarks herein without having to repeat the same and

applying the same to the instant rejection of dependent claims 8 and 9 – noting that claims 8 and 9 (like claims 3-6 and 9) all depend ultimately from claim 1. Applicants further note that Wohlstadter is relied upon in the Office Action to assertedly teach an insertable and/or disposable “cassette.”

However, in view of the foregoing, Applicants note that such (or other) asserted reliance on Wohlstadter does not rectify the above-noted deficiencies of Caillat US (and/or Caillat EP) in view of Landegren. For at least these reasons, Applicants respectfully submit that claims 8 and 9 are non-obvious and patentable over Caillat US (and/or Caillat EP) in view of Landegren and/or Wohlstadter. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 8 and 9 under 35 USC § 103(a) over Caillat US (and/or Caillat EP) in view of Landegren and/or Wohlstadter.

Non-statutory Obviousness-type Double Patenting Rejection

Claims 1 – 6, 8 and 11 are rejected under the non-statutory obviousness-type double patenting basis over claims 1 – 5, 7 and 16 – 22 of U.S. Pat. No. 6,916,614 to Takenaka et al. (hereinafter “Takenaka”) in view of Wilding for the reasons noted at pages 10 – 11 of the previous final Office Action mailed on January 19, 2007 and as maintained in this non-final Office Action as noted at page 2 thereof.

In response, Applicants submit an attorney-of-record Terminal Disclaimer over Takenaka. Accordingly, Applicants respectfully request reconsideration and withdrawal of the non-statutory obviousness-type double patenting basis over claims 1 – 5, 7 and 16 – 22 of Takenaka in view of Wilding.

CONCLUSION

Applicants respectfully submit that the claims (as amended) are patentable and request a written indication of the same.

If any issues remain to be resolved, the Examiner is earnestly requested to contact the undersigned attorney in order to promptly resolve any such issues and to expedite prosecution.

Serial No. 10/624,567

No additional fees are believed to be due. However, if any additional fees are required or an overpayment of fees made, please debit or credit our Deposit Account No. 19-3935, as needed.

Respectfully submitted,

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Enclosures:

Copy of *In re Schreiber*, 128 F.3d 1473, 1477-78 (Fed. Cir. 1997)
MPEP § 2173.05(g)
Fee Transmittal
Terminal Disclaimer